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K120351

MAY - 3 2012

510(k) Summary

(As required by 21 CFR 807.92)

Type of 510(k): Special 510(k)

Submitted By: i-SENS, Inc.
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Prepared Date: February 1, 2012

Device Name: Trade name: CareSens N POP Blood Glucose Monitoring System
Common Name: Glucose Test System

Regulatory Information:

1) Regulation section: 21 CFR 862.1345 Glucose Test System,
21 CFR 862.1660, Quality control material

2) Classification: Class II, Class I

3) Product Code: CGA - glucose oxidase, glucose
NBW - system, test, blood glucose, over the counter
JJX - Quality control material

4) Panel: Clinical Chemistry (75)



Intended Use:

The CareSens N POP Blood Glucose Monitoring System consists of a measuring meter, test strips and control solutions. The CareSens N POP Blood Glucose Meter is intended for use with the CareSens N Single Blood Glucose Test Strips for the quantitative measurement of glucose in capillary whole blood from the fingertip and alternative sites such as the forearm, palm, thigh and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The CareSens Control Solutions are for use with the CareSens N POP Meter and CareSens N Single Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

The CareSens N POP Blood Glucose Monitoring System is intended for self testing, *in vitro* (outside the body) testing at home by people with diabetes as an aid in monitoring the effectiveness of a diabetes control program. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

Device Description:

The CareSens N POP Blood Glucose Monitoring System (BGMS) measures the glucose level in whole blood sample by the meter using a small electrical current generated in the test strips. The system consists of the following: the CareSens N POP Meter, CareSens N Single Test Strips, CareSens Control Solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately), Lancing Device, Lancets, User's manual, Quick reference guide and Logbook.

**Substantial
Equivalence
Information:**

1) Predicate Device name: **CareSens N Blood Glucose Monitoring System**

2) Predicate 510(k) Number : k083468

3) Comparison with Predicate Device:

The modified CareSens N POP BGMS has the following features that are same to the predicate device:

- intended use
- operating principle



- fundamental scientific technology
- operating ranges

The test strips and the control solutions are the same as those of the predicate system, CareSens N Test Strips and CareSens Control Solutions.

The modifications from the predicate device are as follows:

- physical design
- user interface
- software of meter
- software of displaying averages stored in the meter's memory

* Similarities and Differences between candidate and predicate device

Features	CareSens N BGMS (k083468, Predicate Device)	CareSens N POP BGMS (Candidate Device)
Intended Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Enzyme	Glucose Oxidase	Same
Measurement principle	Amperometric method	Same
Test principle	Electro-chemical reaction	Same
Sample	Capillary whole blood	Same
Test Time	5 seconds	Same
Sample volume	Minimum 0.5 µL	Same
Test Range	20 - 600 mg/dL	Same
Temperature	50 - 104°F (10 - 40°C)	Same
Operating Humidity	10 - 90%	Same
Hematocrit range	20 - 60%	Same
Power	Two(2) 3.0 V lithium battery (CR2032)	Same



Battery life	1,000 tests	Same
Memory Capacity	250 blood glucose values	500 blood glucose values
Averaging	14 days	1, 7, 14, 30 and 90 days

Type of Test: Quantitative, Amperometric method, Glucose oxidase (*Aspergillus sp.*)

Test Principle: The reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The Meter converts the electrical current to a concentration of glucose.

Technological Characteristics: The CareSens N POP BGMS has the same fundamental scientific technology as the predicate CareSens N BGMS.

Assessment of Performance Characteristics: When compared with CareSens N BGMS, the basic features of the CareSens N POP BGMS (including the intended use, operating principle, and fundamental scientific technology) are all the same except for the meter's appearance and output value. The CareSens N POP BGMS uses the same test strips (just a different name) and control solutions being used in the CareSens N POP BGMS. So, its performance, safety and effectiveness show results similar to the predicate device. Therefore, to check the features newly added to the CareSens N POP, validation testing was conducted and each feature was checked through the test results on whether or not they operated properly.

Summary of Pre-cleaning and Disinfection: Disinfection studies were performed on the CareSens N POP meter and lancing device by an outside commercial testing service to determine the robustness of the meter and lancing device to the recommended pre-cleaning and disinfection protocol, and its effectiveness in preventing the spread of blood-borne pathogens, using hepatitis B virus (HBV). CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12) was validated for complete inactivation of live virus inoculated on the materials of the meter and lancing device. We have also demonstrated that 260 each of pre-cleaning and disinfection cycles designed to simulate 5 years of use has affected neither



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the performance nor on the external materials for the meter and lancing device.

Conclusion:

Based on the information provided in this submission, the CareSens N POP BGMS is substantially equivalent to the predicate CareSens N BGMS. The CareSens N POP BGMS has met the performance, safety, and effectiveness of the device for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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c/o Hyun Joon Oh
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MAY - 3 2012

Re: k120351

Trade/Device Name: CareSens N POP Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 2, 2012
Received: April 4, 2012

Dear Hyun Joon Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

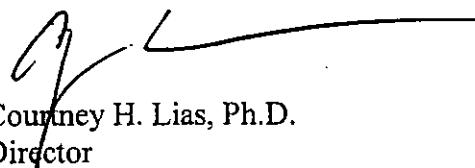
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: CareSens N POP Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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